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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/069,690
Filing Date: August 05, 2002
Appellant(s): ROWLEY ET AL.

Craig M. Bohlken
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 26, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. The statement indicates that there are no related appeals; however, there does appear to be a related appeal. An appeal brief in serial number 10/069,691 has been filed on 6/23/2005 and this application is drawn to similar subject matter.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-9 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder (US 5,132,409) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

Felder discloses a contrast agent for MRI or X-ray imaging comprising a solution of a metal complex, i.e., a macrocyclic ligand and a metal in a vial (non-radioactive, e.g., Gd), see abstract, columns 2-3 see example 17.

Felder discloses that the non-radioactive metal complex contrast agent compositions are contained in vials, but fails to disclose that the vials are silica-coated on the inside.

However it is known in the art that vials that are silica-coated on the inside are useful for pharmaceuticals, as shown by Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica, i.e., pure SiO_2, (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the compositions disclosed by Felder (i.e., non-radioactive metal complex diagnostic agent) by using vials having a silica-coated

inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents, as taught DE '958 and Wather, as stated above. One of ordinary skill in the art would have been motivated to use such improved silica-coated vials for the pharmaceutical compositions disclosed by Felder to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Wather (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

Claims 1, 5, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (US 5,545,396) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

Albert discloses a diagnostic composition comprising a hyperpolarized material, such as, Xe-129 or He-3 gas in glass vials, see abstract and examples.

Albert fails to disclose that the vials are silica-coated on the inside.

However it is known in the art that vials that are silica-coated on the inside are useful for pharmaceuticals, as shown by Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the hyperpolarized diagnostic compositions disclosed by Albert by using vials having a silica-coated inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents, as taught by DE '958 and Walther, as stated above. One of

ordinary skill in the art would have been motivated to use such improved silica-coated vials for the pharmaceutical compositions disclosed by Albert to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Walther (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

Claims 1, 5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larsen (US 6,466,814) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

Ardenkjaer-Larsen discloses a diagnostic composition comprising a hyperpolarized material, such as, hyperpolarized C-13, see column 6, lines 35+.

Ardenkjaer-Larsen fails to disclose that the vials are silica-coated on the inside.

However it is known in the art that vials that are silica-coated on the inside are useful for pharmaceuticals, as shown by Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the hyperpolarized diagnostic compositions disclosed by Ardenkjaer-Larsen by using vials having a silica-coated inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents, as taught by DE '958 and Walther, as stated above. One of ordinary skill in the art would have been motivated to use such improved silica-coated

vials for the pharmaceutical compositions disclosed by Ardenkjaer-Larsen to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Walther (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

(11) Response to Argument

Appellant's arguments filed 7/08/2005 have been fully considered but they are not persuasive.

Appellant asserts in argument "A" that the references fail to disclose, teach or suggest all of the elements of the claims.

This is not found persuasive because the arguments do not state what element is missing from the combination, but only address the references individually and argue that impermissible picking and choosing is used to arrive at the invention.

Appellant asserts that the examiner employed picking and choosing from Felder by picking out -the vial- on which Felder does not even elaborate.

This is not found persuasive because almost all pharmaceuticals and contrast agents are contained in vials. This is routinely how such pharmaceuticals are stored and sold. A reference does not need to claim or elaborate on a specific embodiment for that embodiment to be disclosed. Clearly, Felder discloses non-radioactive metal complex as a diagnostic agent which is contained in a vial. This is all Felder is being used for in the reference. If not contained in vials, it is unclear in what type of container the compositions of Felder would stored. Clearly, they would be contained in vials, as this is specifically recited by Felder. The secondary references provide the significance of diagnostic agents and other pharmaceuticals in silica-coated vials.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper.

Felder teaches metal complex contrast agents and pharmaceuticals that are in vials. The secondary references teach that vials that are coated with silica are advantageous as containers for diagnostic agents and/or pharmaceuticals. Thus, the references are in the same field of endeavor (diagnostic pharmaceuticals) and/or reasonably pertinent to the problem being solved, forming vials of pharmaceutical agents. Clearly, the use of silica-coated vials in a known advantage in the field of pharmaceuticals, and therefore one skilled in the art would have been motivated to obtain these benefits for various pharmaceuticals/diagnostic agents, such as, those disclosed by Felder. Therefore, the motivation to combine arises from the benefits of the prior art.

Appellant asserts that the examiner incorrectly uses the term "contrast agent" in setting forth the rejection of the prior art.

To clarify, it is agreed upon that only the primary references use the term "contrast agent" and also use the term "diagnostic agent." These terms are interchangeable in the art. It is agreed upon the that secondary references broadly teach that the vials are for diagnostic solutions and pharmaceuticals (or medical compositions). This broad teaching is because the specific type of diagnostic or pharmaceutical compositions is not critical to the advantages of the silica-coated vials. The vials are taught to provide advantages for various diagnostic agents or pharmaceuticals, such as, those disclosed by the primary references.

Appellant asserts that since Felder is relatively silent with respect to the vial, that Felder is altogether happy with it and hence there is no need to improve it.

The motivation to improve does not need to originate in the primary reference by itself. The motivation comes from the teaching of the art as a whole. Clearly, an improvement in something used in the Felder invention, not recognized at the time thereof, but before the filing of the instant invention can be used as motivation to improve Felder. This is the situation in the rejection. The art shows that silica-coated vials are an improvement in vials for pharmaceutical use and provide advantages that would have been desired for the pharmaceuticals in vials as disclosed by Felder.

Appellant asserts that the improvements in Felder teach away from the present invention.

This is not found persuasive, as this is not the standard for a reference to provide a teaching away from an embodiment. One improvement is not a teaching away from other. There is nothing to suggest that one skilled in the art would limit themselves to the specific benefits taught Felder. One skilled in the art would be motivated to consider the art as a whole, looking at any possible benefits which may be in the same field of endeavor or reasonable pertinent to the problem being solved. Clearly, Felder teaches the use of metal complexes which are contained in a vial. This is well known in the art. The secondary references teach that pharmaceuticals, including diagnostic agents, benefit from being in silica-coated vials.

Appellant further asserts that a teaching away only requires a teaching that would "lead away" to the claimed invention.

This is agreed upon. However, appellant does not assert what specifically in the art provides a teaching that would lead away from the use of silica-coated vials. It is unclear how "other improvements" in the art provide a teaching away from the use of silica-coated vials. The argument that one skilled in the art would only focus on the improvements of Felder and be motivated to improve those elements ignores other improvements in the art. The art as a whole must be considered. One skilled in the art would not limit improvements only to the general improvements disclosed in a single reference. All of the teachings in the art would be considered. Also, given the disclosure of Felder of contrast agents and pharmaceuticals in vials, one skilled in the art would be motivated to use improved vials.

Appellant asserts that unforeseen problems are solved using the silica vials.

This is not found persuasive because the prior art teaches solving the same problem as discussed in the application. Avoiding the leaching of metals from the glass in the compositions in the advantage taught by DE' '958. Further, the fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

Appellant asserts that there is no teaching in Felder of leaching problems and this is the benefit set forth in DE '958.

The primary reference does not need to state a specific problem in the reference for an improvement in the art to be obvious. The leaching problem is taught in the art, by DE '958, that various pharmaceuticals and diagnostic agents suffer from leaching and that problem can be prevented by using silica-coated vials. Clearly, one skilled in the art would see that the benefit would hold true for various pharmaceuticals and diagnostic agents, as taught by DE '958, such as, the pharmaceutical/diagnostic agents disclosed by Felder.

Appellant also asserts that Walther does not limit the coating to silica, but teaches a few possibilities and there is nothing to point to silica. Appellant further asserts that there are seven possible preferred embodiments and not three as asserted by the examiner..

Whether there are three or seven preferred embodiments does not affect the rejection. Walther does only specifically teach three possibilities (or mixtures thereof), as stated in the examiner's arguments. One skilled in the art would clearly envisage the use of SiO_2 from this very limited number of possibilities shown in the abstract, as well as, the claims.

Appellant asserts that Albert discloses a coating on a glass vessel to reduce relaxation of the gas on the walls and since Albert teaches silicone to solve a problem, which is different from silica, then Albert teaches away from the claimed invention.

This is not found persuasive because this is taken out of context in the invention of Albert. Albert uses the siliconized tubes in phantoms, e.g., in vitro test to check its ability as a contrast agent, and not for storage of the pharmaceutical. The container used herein is for testing the ability of the hyperpolarized gas as a contrast agent. The improvement in the art is taught as storing the pharmaceutical agent. Albert does not teach storage of the diagnostic agent in siliconized vials, but teaches storage of the diagnostic agent in glass vials, see example 3. Nowhere in the cited art is any negative teaching (a teaching away) from the use of silica-coated vials for storage of pharmaceuticals, rather only positive teachings are seen in the cited art. This argument attempts to manipulate the rejection. Albert does use silicone, (admittedly different from silica) in one test aspect of the invention. However, the rejection is based on the storage of the composition in vials, wherein the art as a whole teaches various benefits of storing a wide range of pharmaceuticals and/or diagnostic solutions in vials

that are coated on the inside with silica. The use of silicone in a completely different aspect of the invention, a tube for an in vitro test, does not teach away from using silica-coated vials for storage of the pharmaceutical.

Appellant argues on the difference between silicon, silica, and silicone.

The various differences are acknowledged, but no relevance to these arguments is seen. The art clearly teaches advantages of using silica-coated vials, as claimed. As stated above, the silicone is used for a different purpose in the invention of Albert. This teaching of silicone was not relied on by the examiner at any point and was only raised in appellant's arguments. It was not raised by the examiner because it was not seen as relevant. It is unclear how the difference between silica, silicon and silicone can be used to argue the combination of references, since the rejections of record clearly indicates it would have been obvious to use silica-coated vials (as claimed) because of the advantages provided thereby. The fact the Albert may recite the term "silicone" somewhere in the patent and that silicone is different from silica does not appear to address the rejection.

Appellant further asserts that Schott Glaswerke teaches a wide range of coating possibilities and therefore the combination would not lead to the claimed subject matter.

This is not found persuasive because Schott Glaswerke specifically exemplifies silica, SiO2, see page 3, as well as, claim 3.

Appellant also asserts that Schott Glaswerke only broadly teaches blood as a diagnostic agent.

This is not found persuasive because Schott Glaswerke teaches blood as a specific example, but also teaches the broad use of diagnostic and pharmaceutical agents, see abstract. This broad disclosure supports the examiner's position, that the specific type of pharmaceutical or diagnostic agent was not critical to gaining the improvement with the use of silica-coated vials, as taught by the prior art.

Respectfully submitted,

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Art Unit 1618

mh
December 1, 2005

THURMAN K. PAGE, M.A., J.D.
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